PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

KAV
12/11/04 Resp. to Written Opinion
(Final 1/11/05)

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference see form PCT/ISA/220	Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet) **FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2004/017340	03.06.2004	03.06.2003

International Patent Classification (IPC) or both national classification and IPC
G01N21/27

Applicant
BAYER HEALTHCARE, LLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	D'Alessandro, D Telephone No. +31 70 340-4101

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2004/017340

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was field, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 4,10,16

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 4,10,16 are so unclear that no meaningful opinion could be formed *(specify)*:

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the whole application or for said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-3,5-9,11-15,17-18,21,22
	No:	Claims	19,20
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-3,5-9,11-15,17-18-22
Industrial applicability (IA)	Yes:	Claims	1-3,5-9,11-15,17-18-22
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The subject-matter of claims 4, 10, 16 refers to the determination of the high resolution reflectance values {r}. The definition given in the claims and in the description (par. 13, par. 46) suggests that the elements of {r} depend on the measured reflectance values R of claim 1. This contradicts eqs. (3), (5) of the description, from which it is clear that the elements r_i of {r} are known on the set of reference wavelengths, and cannot be derived from the overall reflectance value R. Due to this inconsistency, the mentioned claims are unclear (Art. 6 PCT), and no opinion on them has been established.
In the following sections, the values {r} have been interpreted as the reflectance spectrum of a target chemical at the reference wavelengths, which is known *a priori*.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO 02/14793 A (DIETIKER THOMAS ; ELEKON IND INC (US)) 21 February 2002 (2002-02-21)
D2: EP-A-0 816 829 (HUTCHINSON TECHNOLOGY) 7 January 1998 (1998-01-07)

The present application does not meet the criteria of Article 33(1) PCT, because

the subject-matter of claims 19,20 is not new in the sense of Article 33(2) PCT, and

the subject-matter of claims 1-3,5-9,11-15,17-18,21-22 does not involve an inventive step in the sense of Article 33(3) PCT.

1.1 The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references applying to this document):

p. 2, last par.; *p. 6, par. 1*	A method of correcting one or more reflectance values when a center wavelength of one or more light sources used to generate corresponding light signals is different from a specified center wavelength for the one or more light sources, comprising:
p. 7, par. 4; *p. 10, par. 3*	defining, for each of the one or more light sources, the center wavelength;
p. 7, par. 2;	determining the actual reflectance for the incident light;
p. 7, par. 4;	determining a correction factor, which is dependent on the center wavelength, in order to compensate the center wavelength error.

The use of the reference spectrum {r} of the target chemical (oxygen in D1 *p. 6, par. 1*), as well as detector sensitivity data for the calculation of the correction factor, is considered implicitly disclosed in D1.
In the light of these disclosures, the difference between the subject-matter of claim 1 and the known method of D1, is the calculation of the correction factor taking into account the power spectral density of the source at a set of wavelengths, rather than just the centroid of the spectrum as in D1. This step allows to compensate the spectral variations with a greater accuracy, in particular when more than one source is used to measure the reflectivity of the sample. Document D2 discloses a method for measuring the absorption spectrum of a sample using light from a plurality of sources (*p. 9, l. 37-44*), in which a spectrum of the incident light is recorded prior to measurement (*p. 7, l. 6-8*). To reach the required detail in the calculation of the correction factor, the person skilled in the art would include this step in the method of D1, obtaining as a consequence the subject-matter of claim 1. The subject-matter of claim 1 does not therefore involve an inventive step (Article 33(3) PCT).

1.2 The subject-matter of independent claims 7,13 is an apparatus whose technical features perform the steps of the method of claim 1. Therefore, the same reasoning as for claim 1 applies, and these claims are considered not inventive.
The applicant should take into account that is not clear neither from the description nor from the claims whether the spectral distribution module (feature A) belongs to the

reflectometer or it is an external device.

1.3 For the same reasons as in 1.2, also the subject-matter of claim 21 is considered not inventive.

1.4 The additional feature:

> the correction factor can be determined for variations of the center wavelength larger than ± 8 nm from the nominal wavelength (cls. 2,8,14)

is implicitly disclosed in D1, given the dynamic range of the wavelength sensor (see *fig. 9*) and the considerations at *p. 6, par. 1.* Document D1 also discloses:

p. 7, par. 2; *fig. 4B*	the one or more light sources comprise LEDS (cls. 3,9,15,22); the light sources and detectors are part of a reflectometer (cls. 6,12,18);

Furthermore, determining the values of {r} at discrete wavelengths intervals (cls. 5,11,17) is the necessary step taken when storing spectra in a memory.
In conclusion, the subject-matter of the mentioned claims does not involve an inventive step.

2. Document D2 discloses the following features of independent claim 19:

fig. 15	A reflectometer, comprising:
p. 9, l. 37-44	a set of light sources;
p. 10, l. 5-12	a set of detectors;
p. 7, l. 20-24	a reflectance assembly configured to direct light signals from the sources onto a sample and reflected light from a sample to the detectors;
p. 13, l. 18-23	a storage device;

p. 14, l. 18-20; a processor
p. 14, l. 46-52

Although the sample in D2 is human skin, no modifications of the disclosed apparatus are required in order to analyze test products as in claim 19. The storage device of claim 19 is defined in terms of the data it is able to store, while the correction function module is defined by the operation it performs rather than by its technical features. Because conventional memory units and processors would be able to serve the same purposes, these definitions are not considered as limiting the subject-matter of the claim. Therefore, in the light of the cited disclosures of D2, claim 19 is not new. The same reasoning applies to dependent claim 20.